UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE RESTASIS (CYCLOSPORINE OPHTHALMIC EMULSION) ANTITRUST LITIGATION	Case No. 18-MD-2819 (NG) (LB) **CONSOLIDATED CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**
THIS DOCMENT APPLIES TO: ALL END-PAYOR PLAINTIFF CLASS ACTIONS	

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Plaintiffs 1199SEIU National Benefit Fund; 1199SEIU Greater New York Benefit Fund; 1199SEIU National Benefit Fund for Home Care Workers; 1199SEIU Licensed Practical Nurses Welfare Fund; American Federation of State, County, and Municipal Employees District Council 37 Health and Security Plan; Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Ironworkers Local 383 Health Care Plan; Self-Insured Schools of California; Sergeants Benevolent Association Health & Welfare Fund; St. Paul Electrical Workers' Health Plan; and United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund (together "Plaintiffs"), on behalf of themselves and all others similarly situated, bring this Consolidated Class Action Complaint against Defendant Allergan Inc. ("Allergan"), and allege as follows.

I. NATURE OF THE ACTION

1. Allergan has reaped billions of dollars in profits from sales of its Restasis dry-eye drops. Restasis is a blockbuster drug and a key revenue source for Allergan that delivered nearly $1.5 billion in 2016 sales. This action arises because, instead of allowing its Restasis pharmaceutical patents to expire in the ordinary course, Allergan carried out a multifaceted scheme to prolong its Restasis monopoly and forestall the generic competition that should have, and absent Allergan's overarching monopolization scheme would have, lowered prices for Plaintiffs and other end-payors. Each additional month of exclusive Restasis sales results in tens of millions of dollars in additional profits for Allergan.

2. Allergan attempted to perpetuate a monopoly to which it was no longer entitled by abusing legal process on a number of fronts. It committed fraud on the Patent Office to gain approval of a second wave of Restasis patents that never should have issued. It filed a set of sham citizen petitions with the FDA to delay approval of competing generic drugs. It pursued baseless infringement litigation against the generic drug makers that sought to compete in the

Restasis market. And, facing a probable invalidity determination in an *inter partes* Patent Office proceeding, Allergan assigned the second wave of Restasis patents to a Mohawk Indian tribe in the hopes that borrowing the tribe's sovereign immunity (in exchange for a multimillion-dollar reverse-licensing fee) could lend its patents the protection that the law does not afford. With these and other acts, Allergan manipulated the legal process to preserve its monopoly profits and foreclose generic entry, thereby preventing more affordable versions of Restasis from coming onto the market and causing end-payors to pay monopoly prices. Allergan's exclusionary conduct violates antitrust and consumer protection laws.

3. Sitting by designation in a patent trial, a judge of the Federal Circuit declared Allergan's second wave of Restasis patents invalid on October 16, 2017. The court found, among other things, that Allergan's presentation to the Patent Office in 2013 "painted a false picture" as to the efficacy of the second-wave patents, "creat[ing] [a] misleading perception . . . . Allergan persuaded the examiner to issue the patent by way of a presentation that was more advocacy than science." The court concluded that "Allergan is not entitled to renewed patent rights for Restasis in the form of a second wave of patent protection" because "clear and convincing evidence" showed that the second-wave patents "are invalid for obviousness." In a separate order, the court stated that "sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities"—but "that is in essence is what the agreement between Allergan and the Tribe does" and "it is clear that Allergan's motivation for the assignment was to attempt to avoid the IPR [*inter partes*] proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity as a bar to those proceedings."

4. Plaintiffs seek injunctive relief to end Allergan's wrongful monopoly conduct, including its efforts to restrain trade through its agreement with the Mohawk Indian tribe, together with damages for purchases and reimbursements of Restasis by Plaintiffs and other end-payors since May 17, 2014—when, but for Allergan's unlawful scheme, the Restasis market would have been opened to competition.

II. JURISDICTION AND VENUE

5. The Court has jurisdiction over Plaintiffs' claim for injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26. The Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), 1337(a), and 1367.

6. This Court has personal jurisdiction over Allergan because it purposefully directed its business activity toward this jurisdiction and had substantial contacts with this jurisdiction, and because Plaintiffs' claims for relief arise from and relate to illegal acts committed by Allergan within this jurisdiction. Plaintiffs paid unlawful overcharges for Restasis and suffered antitrust injury within this jurisdiction.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(a), (b), (c), and (d), and 15 U.S.C. §§ 15(a) and 22. During the Class Period (defined below), Allergan transacted business in this district, and a substantial portion of the activity at issue in this case occurred in this district. Allergan at all relevant times maintained offices and engaged in significant business operations within 30 miles of this Court's Brooklyn courthouse, including Allergan's U.S. "Administrative Headquarters" in Madison, New Jersey and its U.S. sales offices in Jersey City, New Jersey.

8. Allergan's conduct alleged herein occurred within the flow of interstate commerce, including in this district, and was intended to and did have a direct and substantial effect upon such commerce.

9. During the Class Period, Allergan manufactured, sold, and shipped Restasis in a continuous and uninterrupted flow of interstate commerce, which included sales of Restasis in this District, advertisement of Restasis in media in this District, monitoring prescriptions of Restasis by prescribers within this District, and employment of product detailers in this District, who as agents of Allergan marketed Restasis to prescribers in this District. Allergan's conduct had and continues to have a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this District.

III. PARTIES

10. Plaintiffs 1199SEIU National Benefit Fund, 1199SEIU Greater New York Benefit Fund, 1199SEIU National Benefit Fund for Home Care Workers, and 1199SEIU Licensed Practical Nurses Welfare Fund are jointly administered health and welfare funds (collectively, "1199SEIU Benefit Funds"). The 1199SEIU Benefit Funds are among the largest labor-management funds in the nation, providing comprehensive health benefits to hundreds of thousands of working and retired healthcare industry workers and their families. They provide health and welfare benefits to 400,000 members, retirees, and their families, who reside in numerous locations in the United States. As a third-party payor of pharmaceutical claims for their members, the 1199SEIU Benefit Funds are end-payors of Restasis and were thereby injured as a result of Allergan's unlawful behavior. The 1199SEIU Benefit Funds have indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Arizona, California, Connecticut, Florida, Georgia, Indiana, Maryland, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Vermont, and Virginia. When a generic version of a prescription drug is available, 1199SEIU Benefit Funds' members—and 1199SEIU Benefit Funds —typically purchase and/or provide reimbursement for

the generic version. The 1199SEIU Benefit Funds expect that they will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

11. Plaintiff American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan ("DC 37") is located in New York and was established for the purpose of providing benefits to approximately 300,000 active and retired public sector employees and their dependents. As a third-party payor of pharmaceutical claims for its members, DC 37 is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. DC 37 has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Arizona, California, Colorado, Connecticut, Florida, Indiana, Kansas, Massachusetts, New Jersey, Nevada, New York, North Carolina, Ohio, Pennsylvania, Puerto Rico, and Virginia. When a generic version of a prescription drug is available, DC 37's members—and DC 37—typically purchase and/or provides reimbursement for the generic version. DC 37 expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

12. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP Miami") is located in Miami, Florida, and was established for the purpose of providing medical, surgical and hospital care or benefits, including prescription drug benefits, to its members, who are current and retired sworn officers from the City of Miami Police Department and their dependents (providing coverage to over 4,000 individuals). As a third-party payor of pharmaceutical claims for its members, FOP Miami is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. FOP Miami has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, in Arizona, Colorado, Florida, Georgia, Illinois, North Carolina, South Carolina, Tennessee and Texas. When a generic version

of a prescription drug is available, FOP Miami's members—and FOP Miami—typically purchase and/or provides reimbursement for the generic version. FOP Miami expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

13. Plaintiff Ironworkers Local 383 Health Care Plan ("Ironworkers") is located in Wisconsin and was established for the purpose of providing benefits to approximately 500 active and retired ironworkers and their dependents. As a third-party payor of pharmaceutical claims for its members, Ironworkers is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. Ironworkers has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Wisconsin and Minnesota. When a generic version of a prescription drug is available, Ironworkers' members—and Ironworkers—typically purchase and/or provides reimbursement for the generic version. Ironworkers expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

14. Plaintiff Self-Insured Schools of California ("SISC") is a Joint Powers Authority under California law that serves the interests of California public school district members. SISC provides health benefit plans to approximately 300,000 members who reside in numerous locations in the United States. As a third-party payor of pharmaceutical claims for its members, SISC is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. SISC has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Arizona, Arkansas, California, Colorado, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, New York, North

Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia. When a generic version of a prescription drug is available, SISC's members—and SISC—typically purchase and/or provide reimbursement for the generic version. SISC expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

15. Plaintiff Sergeants Benevolent Association Health & Welfare Fund ("Sergeants") is located in New York and was established for the purpose of providing benefits to approximately 4,700 active and 7,600 retired New York City Police Department Sergeants and their dependents. As a third-party payor of pharmaceutical claims for its members, Sergeants is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. Sergeants has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Arizona, California, Colorado, Connecticut, Florida, Kansas, Massachusetts, North Carolina, Nevada, New Jersey, New York, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Washington. When a generic version of a prescription drug is available, Sergeants' members—and Sergeants—typically purchase and/or provide reimbursement for the generic version. Sergeants expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

16. Plaintiff St. Paul Electrical Workers' Health Plan ("St. Paul Electrical Workers"), is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in St. Paul, Minnesota. St. Paul Electrical Workers' Health Plan provides health benefits, including prescription drug benefits, to approximately 6,800 persons, including active plan participants and their spouses and dependents. St. Paul Electrical Workers has indirectly purchased and/or provided reimbursement

for some or all of the purchase price of Restasis during the Class Period, including in Minnesota and Wisconsin. When a generic version of a prescription drug is available, St. Paul Electrical Workers' members—and St. Paul Electrical Workers—typically purchase and/or provides reimbursement for, generic versions. St. Paul Electrical Workers expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

17. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan that currently provides benefits to approximately 1,900 members and 1,700 dependents. UFCW's office—from which it pays health and prescription drug benefits—is located in Illinois. As a third-party payor of pharmaceutical claims for its members, UFCW is an end-payor of Restasis and was thereby injured as a result of Allergan's unlawful behavior. UFCW has indirectly purchased and/or provided reimbursement for Restasis during the Class Period, including in Illinois and Indiana. When a generic version of a prescription drug is available, UFCW's members—and UFCW—typically purchase and/or provide reimbursement for, generic versions. UFCW expects that it will purchase and/or provide reimbursement for Restasis and generic cyclosporine (to the extent it is available) in the future.

18. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business currently located in northern New Jersey, but was located in Irvine, California, during nearly the entire Class Period. Allergan filed and obtained approval of a New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark. Allergan also holds six second-wave patents that it asserts cover Restasis: U.S. Patent No. 8,629,111 (issued Jan. 14, 2014); U.S. Patent No. 8,633,162 (issued

Jan. 21, 2014); U.S. Patent No. 8,642,556 (issued Feb. 4, 2014), U.S. Patent No. 8,648,048 (issued Feb. 11, 2014), U.S. Patent No. 8,685,930 (issued Apr. 1, 2014), and U.S. Patent No. 9,248,191 (issued Feb. 2, 2016) (together, the "second-wave patents"). As of September 8, 2017, Allergan assigned its ownership interest in the second-wave patents to the Saint Regis Mohawk Tribe. The Saint Regis Mohawk Reservation, Akwesasne, spans portions of New York State in the United States and Ontario and Quebec Provinces in Canada.

19. All of the acts and omissions of Allergan detailed herein were part of, and in furtherance of, the unlawful course of conduct alleged herein, and were authorized, ordered, and/or carried out by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and with Allergan's actual or apparent authority.

IV. CLASS ACTION ALLEGATIONS

20. Plaintiffs bring this action under Federal Rules of Civil Procedure 23(a), (b)(1), and (b)(2), as representatives of a class seeking injunctive relief ("Injunctive Relief Class") defined as follows:

> All persons or entities in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Restasis, other than for resale, from May 17, 2014, through the present (the "Class Period").

21. Plaintiffs also bring this action under Federal Rules of Civil Procedure 23(a) and (b)(3), as representatives of a class seeking damages ("Damages Class") defined as follows:

> All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Restasis, other than for resale, in Arizona, Arkansas, California, Colorado, the District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Puerto Rico, Tennessee, Vermont, and Wisconsin from May 17, 2014, through the present, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

22. The following persons and entities are excluded from the Injunctive Relief Class and the Damages Class (together, the "classes"):

(a) Allergan, its officers, directors, employees, subsidiaries, and affiliates;

(b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;

(c) all persons or entities who purchased Restasis for purposes of resale or directly from Allergan or its affiliates;

(d) fully insured health plans, i.e., plans that purchased insurance covering 100% of their reimbursement obligation to members

(e) any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

(f) pharmacy benefit managers;

(g) all judges assigned to this case any members of their immediate families.

23. The class members are so numerous that joinder is impracticable. Members of the classes are widely dispersed throughout the country. The classes include at least hundreds of thousands of consumers and at least thousands of third-party payors.

24. Plaintiffs' claims are typical of the claims of all class members. Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other class members. Plaintiffs and all class members were and will continue to be damaged by the same wrongful conduct, i.e., they paid and will continue to pay artificially inflated prices for Restasis, and were and continue to be deprived of the benefits of competition, as a result of Allergan's conduct.

25. Plaintiffs will fairly and adequately protect and represent the interests of the classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the classes.

26. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

27. Questions of law and fact common to the classes include:

a. whether Allergan willfully obtained and/or maintained monopoly power in the market for Restasis and its generic equivalents;

b. whether Allergan procured the second-wave patents for Restasis by fraud;

c. whether Allergan fraudulently listed the second-wave patents in the Orange Book;

d. whether Allergan initiated and prosecuted baseless litigation against generic competitors;

e. whether Allergan's overall course of conduct unlawfully delayed or prevented generic Restasis from entering the market;

f. whether Allergan maintained monopoly power;

g. whether, and to what extent, Allergan's conduct caused injury to Plaintiffs and the classes;

h. whether the alleged conduct violated the Sherman Act as alleged in the First Claim for Relief;

i. whether the alleged conduct violated state laws as alleged in the Second through Fourth Claims for Relief;

j. what injunctive and other equitable relief is appropriate; and

k. what classwide measure of damages is appropriate.

28. Questions of law and fact common to the Damages Class members predominate over any questions that may affect only individual class members, because Allergan has acted on grounds generally applicable to the entire Damages Class.

29. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

30. Class treatment also is appropriate under Rule 23(b)(1) and/or (b)(2) because:

a. the prosecution of separate actions by individual members of the Injunctive Relief Class would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for Allergan;

b. the prosecution of separate actions by individual members of the Injunctive Relief Class would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other class members not parties to such adjudications or would substantially impair or impede other class members' ability to protect their interests; and

c. Allergan has acted and refused to act on grounds that apply generally to the Injunctive Relief Class such that final injunctive relief and/or declaratory relief is warranted with respect to the class as a whole.

31. Plaintiffs know of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

V. BACKGROUND ON DRUG PATENT PROCEDURES AND PRACTICES

32. Branded drug companies can, and do, obtain valid patents from the U.S. Patent and Trademark Office ("PTO") that cover new prescription drug products. Such patents, awarded on the basis of an applicant's candor and good faith regarding the genuineness of the invention claimed, encourage discovery and development of new medicines, providing—as a reward for true ingenuity—protection from competition by other drug companies for a length of time set under a statute by Congress.

33. Once the lawful periods of patent exclusivity expire on branded drug products, would-be competitors can seek Food and Drug Administration ("FDA") approval to sell generic versions of the branded drug, allowing those companies to manufacture generic products that are just as safe and effective, but far less expensive. With generic competition, the medication becomes affordable.

34. Thus, branded drug companies have a statutory period of time to charge high prices for medications that, in fact, cost little to manufacture, but it is a limited period, after which would-be competitors may enter the market with lower-cost substitutes. And the timing of approval of these competing products depends on, among other things, the truthfulness of the patent information provided by the brand to the FDA.

35. Under the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392, manufacturers who create a new branded drug product must obtain FDA approval to sell it by filing a New Drug Application ("NDA") with the agency. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on patents applicable to that drug. *Id.* § 355(a), (b). The FDA must rely, completely, on the

information provided by the manufacturer and list those patents publicly, so that would-be generic competitors understand the scope of the brand's ostensible patent protection.

36. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the Hatch-Waxman Amendments, in an effort to streamline FDA processes and facilitate competition while incentivizing pharmaceutical manufacturers to innovate. Under the Hatch-Waxman Amendments, competitors wishing to sell a generic equivalent of a branded drug must file an abbreviated new drug application ("ANDA"), which relies in substantial part on the scientific finding of safety and effectiveness included by the branded drug manufacturer in its NDA. 21 U.S.C. § 355(j).

37. Generic manufacturers must wait until the expiration of all listed patents, unless they can certify that their generic product does not infringe the listed patents or that such patents are invalid. Such a certification may permit the brand company to sue for patent infringement—but a brand company may do so only if it has an objectively reasonable basis to claim the patent's protection. The listed patents, would-be competitors' certifications, and brand company's infringement suits all affect the timing of FDA approval of generic equivalents.

38. As a further guard against error in the patent-prosecution process that may result in improvidently issued patents, Congress recently established an "*inter partes* review" ("IPR") process that empowers the Patent Trial and Appellate Board ("PTAB") to review the validity of a previously issued patent. If the PTAB determines that the challenger has a reasonable likelihood of prevailing on at least one of the challenged claims, it may conduct a trial on the claims' validity in which the patent holder is the defendant.

39. This framework produces several basic rules. First, companies seeking to sell a branded drug may only pursue valid patents, with candor and forthrightness in dealing with the PTO. Second, branded drug companies cannot provide false or misleading patent or other drug information to the FDA and wield that information to delay entry of less expensive generic medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Third, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success of the merits; the mere filing of such a lawsuit stalls legitimate efforts to gain market entry. Fourth, federal policy favors prompt invalidation of improvidently issued patents; patent holders cannot knowingly wield invalid patents to thwart competition.

40. Allergan broke all of these basic rules.

A. The Benefits of Generic Drug Competition to the Classes

41. Under the terms of the FDCA and the Hatch-Waxman Amendments, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the branded drug. 21 U.S.C. § 355(j)(2)(A)(iv). Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. *Id.* § 355(j)(8). For drugs that are not intended to be absorbed into the bloodstream, including Restasis, the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed [i.e., branded] drug in safety and therapeutic effect." *Id.*; 21 C.F.R. § 320.24(b)(6). Approved testing methods may include data from live subjects, laboratory studies, or both. 21 U.S.C. § 355(j)(7)(A)(i)(III).

42. The FDA periodically publishes notices in the Federal Register announcing the availability of draft, revised draft, and final versions of product-specific bioequivalence guidance. These notices identify a comment period for draft bioequivalence guidance, and final guidance that allows would-be generic manufacturers to see what approaches to establishing bioequivalence the FDA likely will approve. *See* 21 C.F.R. § 10.115(d)(3). Drugs that meet bioequivalence requirements through an FDA-approved method will be rated "AB," indicating that they are therapeutically equivalent to other drugs with the same rating in the same category.

43. Because generic versions of a corresponding branded drug product are clinically identical commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

44. Since the passage of the Hatch-Waxman Amendments to the FDCA, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded drug prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create an economic dynamic in which the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the branded drug manufacturer, but dramatic savings

for the American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding branded drug sales and (with multiple generics on the market) prices had dropped 85%. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010). As a result, competition from generic drugs is viewed by brand name drug companies, such as Allergan, as a grave threat to their bottom lines.

45. Generic competition enables Plaintiffs and all members of the proposed classes to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the branded drug at a reduced price.

46. Until a generic version of the branded drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the branded drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Branded drug manufacturers, such as Allergan, are well aware of generics' rapid erosion of their brand sales. Branded drug manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

1. Prices drop upon entry of the first AB-rated generic.

47. Experience and economic research show that the first generic manufacturer to enter the market prices its product below the price of its branded counterpart. Every state either requires or permits a prescription written for the branded drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

2. Prices plummet when additional AB-rated generics enter the market.

48. According to the FDA and the FTC, significant price reductions are experienced when generic competitors enter the market. When the first generic enters the market, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near-term retail price reduction of at least 10%. When multiple generic competitors enter the market, competition accelerates and near-term retail price reduction is about 50% with two generics on the market. *See, e.g.*, Luke M. Olson & Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period*, FTC Working Paper No. 317 (2013). Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

49. Soon after generic competition enters the market, the vast majority of the sales formerly enjoyed by the brand shift to the generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

B. Patent Protection for Branded Drugs

1. Patent portfolios for blockbuster drugs

50. There is a predictable pattern to the way a branded drug company will develop its patent portfolios for a blockbuster drug. The first group of patents in the portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the

drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

51. After filing applications for the original patents, the company continues its research and development efforts in the hopes of developing a drug product that eventually could be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drug only if the branded drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. Often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the branded drug company must show non-obvious distinctions.

52. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and—if valid and enforceable—may prove impossible for generic manufacturers to design around while meeting the FDA's bioequivalence criteria. While generic versions of the brand product may be approved by the FDA and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the branded drug company has no lawful means of trying to prevent competitors from entering the market.

53. Therefore, a typical patent portfolio for a branded drug has its most significant patents issuing first; over time, the later-issued patents generally become increasingly narrow

and more difficult to obtain. Even if the branded drug manufacturer obtains that narrower coverage, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics, thus preventing the branded drug company from satisfying its burden of proving infringement to keep generics out of the market.

2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties designed to protect the public interest in the PTO's issuance of valid and lawfully obtained patents

54. Because patents often enable a branded-product manufacturer to exclude competition and charge supracompetitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

55. Patent prosecutions are non-adversarial. To help ensure that the "public interest is best served" through the PTO's issuance of patents that are valid and lawfully obtained, patent applications are subject to various special oaths and duties. Among these various special oaths and duties is the Duty of Disclosure, Candor, and Good Faith, which requires the applicant to disclose to the PTO of "all information known . . . to be material to patentability" including with respect to prior art. *See* 37 C.F.R. § 1.56. And this duty extends not only to each and every named inventor on the patent application but to each and every "attorney or agent who prepares or prosecutes the application" as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* § 1.56(c). Where fraud on the PTO "was practiced or attempted" or the Duty of Disclosure, Candor, and Good Faith "was violated through bad faith or intentional misconduct," no patent should be granted. *Id.* § 1.56(a).

C. New Drug Applications (NDAs) and Patent Listings in the FDA's Orange Book

56. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug companies that wish to sell a new drug product must file with the FDA a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355 (a), (b).

57. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA then publishes a list of those patents in the publicly available Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the branded drug. 21 C.F.R. § 314.53 (c)(2)(ii).

58. The brand name drug manufacturer can submit its patents for Orange Book listing by filing with the FDA a Form 3542. *Id.* § 314.53 (c)(1). Under the FDA rules, the branded manufacturer is only permitted to list patents that are reasonably enforceable. Form 3542 expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (i.e., a situation where no patents could be reasonably asserted in an infringement lawsuit). Form 3542 likewise requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

59. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the authority or resources to verify the manufacturer's representations for accuracy or trustworthiness and relies completely

on the manufacturer's truthfulness about the validity and applicability of any Orange Book–listed patents.

D. Abbreviated New Drug Applications (ANDAs), Orange Book–Related Generic Manufacturer Certifications, and Related Litigation

60. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the FDA that may rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the blood stream at a similar rate over a similar period of time, are expected to be equally safe and effective.

61. At the same time, the Hatch-Waxman Amendments sought to protect pharmaceutical companies' incentives to create new and innovative products by, among other things, permitting a branded drug company to file a patent infringement lawsuit in good faith against a generic before the generic actually brought its product to market.

62. The Hatch-Waxman Amendments substantially achieved both goals, advancing the rate of generic product launches, and ushering in an era of historically high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with

generic drugs accounting for 18.6% of prescriptions. By 2016, total prescription drug revenue had soared to over $450 billion, with generic drugs accounting for 89% of total prescriptions.

1. The Hatch-Waxman Amendments provide for an automatic 30-month stay of FDA ANDA approvals to resolve legitimate patent-infringement claims

63. The Hatch-Waxman Amendments created a procedural mechanism to resolve patent disputes between manufacturers of branded and generic drugs before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Amendments permitted a branded drug manufacturer to sue a generic for patent infringement even if their products had not launched yet.

64. Once one or more patents are listed in the Orange Book as pertaining to the branded drug, a generic manufacturer seeking FDA approval of a generic equivalent must certify that the generic drug addressed in its ANDA will not infringe any of those patents. A generic manufacturer can make one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA;

ii. that the patent for the brand name drug has expired;

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product. 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

65. If a generic manufacturer files a certification based on the last of these options (a "paragraph IV" certification), the owner of the patent—generally the branded drug manufacturer—can sue the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic filer within 45 days of

receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *Id.* §§ 355(c)(3)(C), (j)(5)(B)(iii). Until one of those conditions is met, the FDA cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

66. The branded drug manufacturer may file patent-infringement claims more than 45 days after receiving the paragraph IV certification, but doing so would not trigger the automatic 30-month stay of FDA approval.

2. The Hatch-Waxman Amendments incentivize generic manufacturers to challenge questionable patents before launch by awarding 180-day exclusivity to the first paragraph IV–certified ANDA filer

67. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a paragraph IV certification is eligible for 180 days of market exclusivity. This means that other, secondary ANDA-filers will not be able to launch their own generic products for at least six months after the first generic—known as the "first-filer"—launches its product.

68. The FDCA defines "first applicant" as "an applicant that, on the first day on which a substantially complete application containing a [paragraph IV] certification . . . is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV] certification . . . for the drug." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

69. During this 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, this 180-day

exclusivity period is very valuable and it is often the case that most of a first-filer's profits are earned during this 180-day exclusivity period. *FTC v. Actavis*, 133 S. Ct. 223, 229 (2013).

70. If the only versions of a drug on the market are the branded drug and the first-filer's product, then the first-filer prices its product below the brand product, but not as low as if it were facing competition from other generics. In these circumstances the first-filer's product may compete only with the branded drug, and because the branded drug company rarely drops the branded drug price to match the first-filer's, the first-filer does not face the kind of price competition that arises when additional generic competitors enter the market.

E. The Citizen Petition Process

71. Pharmaceutical companies have multiple avenues and opportunities through which to communicate their views to the FDA. For example, the FDA holds public advisory meetings, which can be requested by pharmaceutical companies, to address issues regarding specific drug products or more generalized issues that pertain to many products. Additionally, there are industry and FDA fora for discussion that permit interaction and debate.

72. Pharmaceutical companies, like members of the public, may file a petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, any form of administrative action. This mechanism, created by Section 505(j) of the FDCA, is commonly referred to as a citizen petition or "FDA Petition." Citizen petitions are intended to convey for the FDA's consideration in terms of its policies and procedures genuine concerns about safety and scientific or legal issues regarding an FDA-regulated product any time before, or after, market entry.

73. A citizen petition may be filed to request that the FDA take action regarding drug approval requirements, including those involving generic drugs. To move the FDA to grant this type of request, the petition must include supportive, clinically meaningful data, and the

requested relief must be consistent with the FDA's authority and with the Hatch-Waxman Amendments' statutory and regulatory framework.

74. The FDA must deploy the resources necessary to timely respond to a citizen petition. FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days after the date on which the petition was submitted. 21 C.F.R. § 10.30(e)(2). That response may be to approve the request in whole or in part, or to deny it. The Commissioner may also provide a tentative response with a full response to follow.

75. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. A response to a citizen petition and the approval of generic drugs are each considered final FDA actions that can be appealed under the Administrative Procedures Act. A petitioner who does not agree with the FDA's response to a petition can sue the FDA (and many have) and seek to have the FDA's response overruled as arbitrary and capricious. The FDA therefore needs to have a complete administrative record reflecting that its response was based on sound science, in part, to defend itself in any subsequent appeal. The FDA also must base its decisions about the fundamental safety and efficacy of drug products on sound science to protect users of those products.

76. These activities strain the FDA's limited resources, and citizen petition reviews can delay FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

77. Indeed, in July 2006, Gary Buehler, R.Ph., former FDA Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, noted that of 42 citizen petitions

raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Of these 42, only three petitions led to a change in FDA policy on the basis of data or information submitted in the petition.

78. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years, as branded drug companies have sought to compensate for dwindling new-product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for more than a year, long after the branded drug manufacturer received notice of the ANDA filing, and have had the (intended) effect of delaying the approval of generic drugs while the FDA evaluated the citizen petition. One recent empirical study found that "[m]any citizen petitions from competitor companies appear to be last-ditch efforts to hold off generic competition. In fact, the most common grouping of petitions was those filed within six months of generic approval." Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 70 (2017).

79. Delaying generic competition is a lucrative strategy for a branded drug manufacturer. Given the marketplace's preference for generic over branded products, the cost of filing a citizen petition may be trivial compared to the value of securing even a few months of generic entry delay.

80. FDA officials have further acknowledged abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application," and instead "try to delay the approval simply by compelling the agency to take the time to consider arguments

raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

81. It is well known in the pharmaceutical industry that it is FDA practice to withhold ANDA approvals until after its consideration of, and response to, a citizen petition is complete. On this subject, Director Buehler acknowledged that, with respect to the FDA's Center for Drug Evaluation and Research ("CDER"), "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

82. In an effort to address the potential anticompetitive abuse of the citizen petition process, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which was enacted on September 27, 2007. Pub. L. No. 110–85, 121 Stat. 823 (2007). The FDAAA adds new section 505(q) to the FDCA. Section 505(q)(1)(A) provides that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A)(ii). The FDAAA did not provide the FDA with additional resources to enable it to more promptly respond to petitions, however. Instead, the FDAAA provides only that the FDA must communicate any ANDA-approval delay within thirty days of its determination that a delay is necessary. Thus, a branded drug manufacturer may still be able to delay generic approval while the FDA considers whether the relevant citizen petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition has any merit. In the high-stakes world of pharmaceuticals, even relatively short delays can cost generic firms and drug purchasers millions of dollars in lost sales and prescription drug overpayments, respectively.

83. Even after several years of experience under the FDAAA, the FDA continues to express concerns that citizen petitions are being filed for the purpose of delaying ANDA approvals:

> FDA will continue to gain additional experience and monitor trend data in the FY 2012 reporting period to assist Congress in determining whether section 505(q) is accomplishing the stated goals of the legislation. Based on the petitions that FDA has seen to date, however, the agency is concerned that section 505(q) may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive dug products.[1]

84. Independent research has confirmed the FDA's view. One recent study found that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, 21 U.S.C. § 355(q), which are now the type most often employed to oppose generic entry—and the type Allergan filed here. *See* Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 332-33, 333 tbl. 4 (2016).

F. Proceedings Before the Patent Trials and Appellate Board (PTAB)

85. In 2011, Congress passed the Leahy-Smith America Invents Act to address a widely held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy. Pub. L. 112–29, 125 Stat. 284 (2011). A centerpiece of the Act was the creation of new IPR proceedings, by which members of the public could challenge improperly issued patents and have them eliminated more quickly and inexpensively than through patent litigation. IPR proceedings also bore the promise of a review by technically educated members of the PTAB who are deeply familiar with the sciences at issue in any particular proceeding.

[1] Report to Congress, Fourth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011, Department of Health and Human Services, Food and Drug Administration.

86. The Act allows the PTAB to review existing patents and extinguish those rights in an adversarial trial process. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to reconsider the PTO's issuance of a patent and invalidate it on the ground that it was obvious or anticipated by prior art.

87. The PTAB will grant a request for an IPR only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). If it institutes an IPR, the review is conducted before a panel of three technically trained administrative PTAB patent judges.

88. The PTAB must decide the review within one year of the institution date—significantly faster than invalidity issues would generally be adjudicated in a trial before a district court. Notably, the IPR process can and frequently does take place simultaneously with parallel district-court infringement litigation. The IPR process thus provides a speedy and economical mechanism for an accused patent infringer to challenge a wrongfully issued patent.

89. PTAB trial proceedings have become an exceedingly effective method of challenging improperly granted patents—at least 84% of patents reaching a final written decision in PTAB validity challenges are adjudicated to have at least one invalid claim, and 69% have had *all claims* cancelled as invalid.[2] Given the high likelihood of claim cancellation once an IPR has been instituted, IPR proceedings have earned the moniker "patent death squads."

II. FACTUAL ALLEGATIONS

A. The FDA Approves Allergan's Restasis

90. Cyclosporine treats dry eye disease, also known as keratoconjunctivitis sicca, a painful and irritating condition involving abnormalities and deficiencies in the tear film of the

[2] Steve Brachmann & Gene Quinn, *Are more than 90 percent of patents challenged at the PTAB defective*?, June 14, 2017, http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/. (last visited Nov. 1, 2017).

eye. Simply put, dry eye disease is the failure to produce tears in the normal fashion, in a way that can seriously threaten a patient's eyesight. The condition causes patients discomfort, including a sandy or gritty feeling in the eye, blurred vision, and infection. More severe cases of dry eye disease can involve or precipitate inflammation with serious potential damage to the ocular surface. Dry eye disease disproportionately afflicts the elderly, menopausal women, and those with systemic diseases such as Sjogren's syndrome, rheumatoid arthritis, lupus, and diabetes.

91. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A,[3] an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is one of the most widely prescribed drugs in the world; last year, in the United States alone sales of Restasis were nearly $1.5 billion.

92. In 1993, Allergan licensed from Sandoz, Inc., the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent No. 4,839,342 issued to Renee Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle, in this case topical administration. The Kaswan patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

93. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine), together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in

[3] Cyclosporin A is sometimes spelled "cyclosporine" to distinguish it from other cyclosporins, such as cyclosporins B, C, and D. See U.S. Pat. No. 4,839,342, col. 3, ll. 7-11.

two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "Ding I," named after the inventor Shulin Ding), which issued in 1995. Ding I contained four examples, the first two of which included multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. Ding I stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12. The formula Allergan eventually settled on and sold as Restasis falls within the range of values disclosed and claimed in the Ding I patent.

94. The second patent, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method for alleviating dry eye–related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

95. Allergan then began clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (e.g., 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the periodical article Dara Stevenson et al., *Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-Severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-

severe dry eye disease and mitigated dry eye disease's effects on vision-related functioning. All tested concentrations were safe and effective in increasing tearing in certain patient groups.

96. Notably, Stevenson concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and the formulations containing greater amounts of cyclosporine—efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson's study suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

97. Phase 3 trials did just that, with the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000). Phase 3 confirmed the results of Phase 2 and found the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over the patient's baseline, suggesting that it was a contributing factor to the formulations' success.

98. There was no statistically significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

99. Following the Phase 3 study, Allergan filed an NDA with the FDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The proposed commercial product, which is Restasis, would contain all of the components of the

Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the application in December 2002, authorizing the sale of Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs." Since its launch in 2003, Restasis has been a highly successful product for Allergan.

B. Allergan Prosecutes Serial Patent Applications in an Effort to Obtain Additional Patents to Extend the Restasis Monopoly

1. The PTO repeatedly rejects Allergan's serial efforts to obtain additional patents for "new" combinations of castor oil and cyclosporine that were in fact obvious in light of prior art

100. For over a decade following the FDA's approval of Allergan's Restasis NDA, Allergan filed a variety of patent applications focusing on patenting combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations, with no statistically different outcomes based on the particular combination. Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and the PTO examiner rejected the remaining claims based in part on obviousness in light of Ding I.

101. Allergan then amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis. The PTO examiner again rejected the application, because the emulsion's formulation was obvious, the castor oil–cyclosporine ratio having fallen within the

range claimed in Ding I. Allergan appealed and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but it added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

2. In 2009, Allergan concedes that all its "new" cyclosporine/castor oil combination claims are obvious in light of Ding I

102. In a June 2009 filing with the PTO, Allergan contradicted its earlier patentability claims, and admitted with respect to both the '857 and '177 applications that the various composition claims were obvious in light of the examples of potential formulations listed in Ding I. Allergan wrote that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan, in its own words, "concede[d] that in making this selection (0.05% cyclosporin and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." According to Allergan, the composition claims advanced by the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal.

103. After canceling the previous claims on the '857 application, Allergan tried once more to add to that application a new claim regarding another composition of cyclosporine and castor oil. As with all the other composition claims, the PTO examiner on September 1, 2009, rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the '857

application. The '177 application ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

3. Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of new continuation applications, all deriving from the '177 application

104. Having repeatedly failed to convince the PTO to grant patent protection over various "new" composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, in August 2013, Allergan filed six additional continuation applications deriving, directly or indirectly, from the '177 application. These six additional applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As a federal district court invalidating the patents that subsequently issued from these applications later found: "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and keratoconjunctivitis sicca after the expiration of the Ding I patent in 2014." *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455, 2017 WL 4803941, at *10 (E.D. Tex. Oct. 16, 2017).

105. In initiating these 2013 applications, Allergan tried to retract its prior concession that various cyclosporine–castor oil combinations were obvious in light of Ding I, claiming to have new data supporting patentability, based on "unexpected" results showing the claimed Restasis formulation to be particularly effective. Such "unexpected" results would have been one of the few avenues available to Allergan to get around the fact that Ding I, the prior art, had disclosed the range, and that from within that range there was reason to select the Restasis formulation. The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

106. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists, including Dr. Rhett M. Schiffman. According to Allergan, these declarations demonstrated that the Restasis formulations reflected in the 2013 applications outperformed other combinations to a "surprising" extent not anticipated by Ding I and other prior art. Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated "surprising" test results:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . . . Exhibits E and F also illustrate that the claimed formulations also demonstrated a *4-fold* improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a *4-fold* increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

Id. at * 11 (quoting Allergan's representation of Dr. Schiffman's declaration to the PTO).

107. Based on Allergan's representation of Dr. Schiffman's discovery and the declaration itself, the PTO examiner reversed course and allowed the patents to issue with respect to all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and in 2016 as U.S. Patent No. 9,248,191 ("the '191 patent"). These are the "second-wave patents" at issue here.

4. Allergan's new 2013 data and "unexpected results" were neither new nor unexpected, and fraudulently induced the PTO to grant the second-wave patents

108. In reality, however, the statements and data reflected in Dr. Schiffman's declaration that Allergan portrayed to the PTO examiner as presenting new and unexpected results were not new. Instead, Dr. Schiffman's declaration consisted of statements plagiarized from an article published in a well-known medical journal thirteen years earlier, Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article"). The Sall Article had relied on Allergan's own Restasis Phase 3 clinical trial data that it had recorded in the 1990s. In fact, this was the very periodical that publicized Allergan's Phase 3 clinical results.

109. Not only was the "new" 2013 data not actually new, it did not actually demonstrate unexpected results. As the district court that invalidated the second-wave patents found:

> [Allergan's] presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

Allergan, 2017 WL 4803941, at *64.

110. Moreover, to reach the "unexpected results," Allergan mischaracterized the Phase 2 study as suggesting that the 0.1% formulation worked better than the 0.05% formulation, when in fact, as the district court recognized in invalidating the second-wave patents, "[t]he small size of the Phase 2 study makes it difficult to draw reliable conclusions about the relative efficacy of different formulations." *Id.* at *23. The Phase 2 study, in fact, was never meant to compare the

two formulations' comparative efficacy—only the general safety and efficacy of the various formulations—and Allergan's "flawed effort to convert the Phase 2 study into an assessment of the relative efficacy of the 0.05% and 0.1% cyclosporine formulations lies at the heart of the problem with its 'unexpected results' analysis." *Id.*

111. In submitting the 2013 continuing applications, Allergan sought new patent protection on substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of prior art. The PTO examiner granted the 2013 claims only upon reliance on Allergan's Shiffman Declaration and Allergan's characterizations of "new" data and surprising results not contemplated by the prior art.

112. Allergan made these representations and characterizations, both affirmatively and by omission, with the intent to deceive the PTO. Allergan's representations and characterizations were material and fraudulently induced the PTO to grant the second-wave patents. As the district court found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO . . . and the fact that the examiner concluded that unexpected results had been shown . . . the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, *painted a false picture* of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation *created the misleading perception* that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of unexpected results to be entitled to no weight, based as it was on evidence that *did not accurately depict* the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

Id. at 82-83 (emphasis added).

113. Had Allergan made clear to the PTO examiner that the Shiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the

2013 applications for the same reasons it had denied every prior application: the claims presented were all obvious in light of the prior art.

C. Allergan Wrongfully Lists the Invalid Second-Wave Patents in the Orange Book, Creating Confusion and Delay in the ANDA Approval Process, While Providing a Path to Filing Sham Patent Infringement Suits Against Would-Be Generic Competitors to Further Delay Generic Entry

114. The second-wave patents issued beginning on January 14, 2014, starting with the '111 patent, which Allergan immediately submitted for listing in the Orange Book. This listing required any ANDA filer seeking to market a generic version of Restasis to file a certification as to that "new" patent.

115. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, the agency had received at least one ANDA for a generic version of Restasis. Up until the listing of the second-wave patents, ANDAs may have been filed with paragraph II or III certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, just months away. Had Ding I simply expired in May 2014 without Allergan's machinations, any paragraph II or III certified ANDAs would have been approved, generic cyclosporine would have been available, and the competition to Restasis would have created immediate benefits to the classes in the form of lower prices.

116. Instead, all prior ANDA filers now had to amend their ANDAs to include paragraph IV certifications with respect to the '111 patent (and eventually the other second-wave patents). And the confusion Allergan created by its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received—i.e., accepted for review—any prior ANDA certifications likely was different than the order in which the agency received the paragraph IV certifications with respect to the second-wave patents, creating various first-filer status uncertainties.

117. The various uncertainties created by Allergan's actions—regarding which ANDA filer was eligible for first-filer status and the attendant 180-day exclusivity period—led the FDA on July 28, 2015, to distribute a "Dear ANDA Applicant" letter soliciting the views of all the ANDA filers regarding which ANDA applicant should be deemed the first-filer.[4] Allergan submitted an unsolicited response intended to sow still further confusion (discussed below).

118. As of March 2018, the FDA has yet to publicly opine on the Restasis first-filer issue. In addition to delaying the FDA's ANDA approval process pending resolution of the first-filer issue, Allergan's wrongful Orange Book listings also enabled Allergan to sue all ANDA applications that filed paragraph IV certifications with respect to the second-wave patents for infringement and trigger the automatic stay of any FDA approval of such ANDA for up to 30 months. In contrast, paragraph II– or III–certified ANDAs are not subject to that automatic 30-month stay of FDA approval.

119. Allergan knew when it listed the second-wave patents in the Orange Book that such patents were invalid, having followed from misrepresentations in Dr. Schiffman's declaration, but nevertheless would provide Allergan a basis to delay generic competition to Restasis beyond May 2014 and otherwise would create confusion that would further chill the FDA's ANDA approval process.

120. No objectively reasonable pharmaceutical company would have listed the second-wave patents in the Orange Book while knowing they were invalid, or created and exacerbated

[4] To the extent Watson Laboratories, Inc., may have been the first-filer, as is suggested by SEC disclosures made by Allergan, Inc., Watson's subsequent corporate mergers compounded any first-filer uncertainties. Watson Laboratories' parent, Watson Pharmaceuticals, acquired Actavis, Inc., in 2013, and operated thereafter as Actavis, which in 2015 acquired Allergan, and thereafter operated as Allergan. In August 2016, Allergan's Actavis generic business was acquired by Teva, another ANDA applicant that had provided Allergan with notice of its paragraph IV certifications as to the second-wave patents in July 2015 (but appears to have filed its original ANDA at or near the time of Watson's original ANDA filing in 2011). The extent to which Watson's Restasis ANDA factored into the various mergers as another means to protect the nearly $1.5 billion per year Restasis monopoly is presently unknown.

confusion about which manufacturer was the first-filer—confusion that would not have existed had Allergan simply let the Ding I patent expire. But Allergan listed the second-wave patents without regard to their validity and created the potential for regulatory exclusivities that should not have existed, with the purpose of impeding competition.

D. Allergan Files Sham Patent-Infringement Suits to Delay Generic Entry

121. In response to Allergan's Orange Book listings, and as Allergan had planned, generic competitors provided paragraph IV certifications as to the second-wave patents. Generic manufacturers Akorn, Mylan, Teva, Apotex, and Innopharma all submitted paragraph IV certifications within weeks of each other beginning in July 2015, asserting that the second-wave patents were either invalid or non-infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate basis to enforce them. Yet Allergan responded to each of the above paragraph IV certifications by filing patent infringement actions in the federal district court of the Eastern District of Texas, beginning on August 24, 2015. (The court later joined subsequent paragraph IV certificants.)

122. Allergan's infringement suits triggered the automatic 30-month stay of any FDA final approval of the ANDAs submitted by the defendant generic manufacturers in the suits.

123. After a bench trial in August, the district court issued an order on October 16, 2017, finding the second-wave patents invalid based on obviousness. In a thorough 135-page post-trial Findings of Fact and Conclusions of Law, the court found that Allergan had secured these Patents "by way of a presentation that was more advocacy than science." *Allergan*, 2017 WL 4803941, at *64. The court found particularly compelling the 2009 concessions, the fact that Allergan's "unexpected" results were foreseeable based on the early cyclosporine studies, and that in any event, the "new" Restasis formulation claimed by the second-wave patents had statistically the same efficacy as one of the prior art examples in Ding I.

124. The court also dismissed other arguments Allergan made at trial, including assertions that the surprise results arose from a difference between the Phase 2 and 3 studies, and that there were objective, valid reasons for issuing new patents:

> While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [second-wave] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.

Id. at 134-35.

125. Allergan brought these infringement suits even though (i) it had conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the second-wave patents) were obvious in light of Ding I, and (ii) Allergan knew it had obtained the second-wave patents only through its fraudulent misrepresentations to the PTO. Accordingly, there was no objective merit to any of these infringement suits.

126. The objective merits were irrelevant, however, to Allergan's true purpose. Allergan filed those suits not to advance the interests of protecting legitimately secured patents but to improperly use government process and the Hatch-Waxman Amendments to delay generic competition to its Restasis monopoly. Indeed, Allergan's subjective intent in filing these suits is evident from the complaint it filed. In its prayer for relief, Allergan demanded that the district court order, notwithstanding any lack of authority to do so, that "the effective date of any FDA approval" of any Restasis ANDA—not just the ANDA owned by the generic manufacturer defendants in the case—be "a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity" of the second-wave patents. *See* Amended Complaint at 127, 129, 131, 132, *Allergan, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*,

No. 2:15-cv-01455 (E.D. Tex. Feb. 18, 2016), ECF No. 96. Essentially, Allergan was asking the court to insert itself into the FDA's ANDA review process to forestall competition.

127. Allergan knew that the mere filing of patent infringement suits (however baseless) would immediately trigger the automatic 30-month stay of FDA final approval of any generic cyclosporine product. For a $1.5 billion a year franchise, every extra month Allergan could postpone generic competition would add another $125 million to its revenues.

E. Allergan Abuses the FDA's Citizen Petition Process to Delay Generic Entry

128. In early 2014, just as the PTO started issuing the second-wave patents, Allergan started to bombard the FDA with groundless, repetitive, and serial petitions seeking to delay the FDA's approval of any Restasis ANDA.

129. On January 15, 2014, the day after Allergan listed the first of the second-wave patents in the Orange Book, Allergan submitted a citizen petition relating to the FDA's non-binding June 2013 draft guidance that provided Restasis ANDA applicants with two options to demonstrate the bioequivalence necessary for ANDA approval. One of those options, the in vitro option, did not require the kind of very time-consuming and expensive in vivo clinical endpoint studies that brand manufacturers generally must undertake in support of the branded drug's NDA (but that, due to their prohibitive expense, generic manufacturers ordinarily do not undertake in support of their ANDAs). Neither draft nor final guidance are required for the FDA to approve an ANDA, and the agency often approves ANDAs without first issuing guidance, but the publication of draft guidance and request for comment on the different options showed the FDA was well on its way to identifying the conditions for approving Restasis ANDAs.

130. Allergan filed a superseding citizen petition on February 28, 2014. Allergan's citizen petition explicitly requested that the FDA "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical

trials to demonstrate bioequivalence." Allergan Feb. 28, 2014, Citizen Petition at 1. Allergan made six sweeping requests, ranging from asking that the FDA withdraw the June 2013 guidance to listing various onerous conditions the FDA should require and/or undertake before approval of any Restasis ANDA. It based its requests on Section 505(q) of the FDCA, namely, it contended "a delay is necessary to protect the public health."

131. Allergan's views were not new to the FDA—the views expressed in its February 28, 2014, petition were entirely redundant to its comments on the draft guidance, which it had submitted on August 17, 2013. There, in a 43-page comment, Allergan argued that the FDA could not approve any Restasis ANDA that demonstrated bioequivalence through the in vitro option provided in the draft guidance and requested that the "FDA replace the Draft Guidance with a revised guidance document that explains in vivo comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to RESTASIS." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013.

132. In support of its February 2014 citizen petition, Allergan also referenced the fact that "[n]umerous physicians submitted comments, drawn from their clinical experience, criticizing the draft guidance's in vitro approach," which Allergan dubbed "strikingly one-sided" in support of Allergan's position. But Allergan did not disclose to the FDA its relationship to those commenting physicians. For example, Dr. Stephen Pflugfelder filed a comment on the draft guidance posted on August 9, 2013, stating his concern that the FDA might "approve generic cyclosporine ophthalmic emulsions without human clinical trials." Neither Allergan nor Dr. Plugfelder disclosed that Allergan paid him roughly $70,000 in 2013 for his "consulting"

services and "travel and lodging," generally and specifically relating to Restasis.[5] Similarly, in a comment dated August 16, 2013, Dr. Jai G. Parekh claimed he was "surprised by the recent FDA-related issue on bioequivalence." Neither Allergan nor Dr. Parekh disclosed that Allergan paid him nearly $9,000 in 2013 for his services relating to Restasis and other drugs, $2,500 of which was explicitly relating to consulting on Restasis and paid to him five days after he submitted his comment.[6] Dr. Marc Bloomenstein's comment, posted August 15, 2013, similarly fails to disclose 144 payments from Allergan in 2013 amounting to $47,557, all but two of which explicitly related to Restasis.[7]

133. Recycling its views, and those of its paid consultants, in its February 2014 citizen petition, Allergan again urged the FDA not to approve any Restasis ANDAs not supported by in vivo clinical endpoint studies using human subjects, professing concern that "rushing prematurely to approve a proposed generic drug poses a risk to patient health and could weaken the public's trust in generic drugs as a class." Allergan Feb. 28, 2014, Citizen Petition at 4. But to its shareholders, Allergan cited its citizen petition submissions as an example of what it was doing in response to "intense competition from generic drug manufacturers." See Allergan, Inc., U.S. Securities and Exchange Commission Form 10-K for FY Ended 12-31-2014 at 12, 48.

134. In a November 20, 2014, letter, the FDA substantively rejected the six requests in Allergan's citizen petition. The FDA granted Allergan's request only to the limited extent that Allergan requested notice and an opportunity to comment on the FDA's recommended bioequivalence methodology, and agreed to explain the scientific basis for allowing ANDA

[5] *See* ProPublica, Dollars for Docs—Stephen C Pflugfelder, https://projects.propublica.org/docdollars/doctors/pid/356009 (last visited Oct. 30, 2017).

[6] *See* ProPublica, Dollars for Docs—Dr. Jai Parekh, https://projects.propublica.org/docdollars/doctors/pid/37605 (last visited Oct. 30, 2017).

[7] *See* ProPublica, Dollars for Docs—Dr. Marc Bloomenstein, https://projects.propublica.org/docdollars/doctors/pid/25861 (last visited Oct. 30, 2017).

applications to rely solely on in vitro studies to show bioequivalence, all of which the FDA's denial of the citizen petition itself provided. Thus, the FDA's agreeing to allow comment was in no sense a "win" for Allergan, and the FDA specifically refuted Allergan's argument that the FDA was legally required to use notice-and-comment rulemaking. Ltr. from J. Woodcock to D. Burrow Re: Docket No. FDA-2014-P-0304, at 27-29 (Nov. 20, 2014) ("None of your legal contentions has merit . . . ."). Similarly, the FDA's response to Allergan's request for an explanation was no achievement of an end-goal for Allergan. It simply stated why Allergan was wrong and why, therefore, the FDA rejected the petition in its entirety.

135. In its rejection of Allergan's substantive requests, the FDA explained the important policy goals underlying its reasoning:

> The Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data enables FDA to effectuate several long-recognized policies that protect the public health: (1) refraining from unnecessary human research when other methods of demonstrating bioequivalence meet the statutory and regulatory standards for approval; (2) permitting the Agency to use the latest scientific advances in approving drug products; (3) protecting the public by ensuring only safe effective generic drugs are approved for marketing; and (4) making more safe and effective generic drugs available.

Id. at 7-8 (citations omitted). The FDA then explained that for drugs that are primarily absorbed systemically, in vivo studies are often preferred, but that these studies are "usually of limited utility for locally acting, non-systemically absorbed drug products," like Restasis. *Id.* at 8. The 2013 draft guidance recommended either type of study, but noted that the "modest efficacy demonstrated by Restasis" meant that "a bioequivalence study with clinical endpoints … may not be feasible or reliable." *Id.* at 11.

136. The FDA also observed that the kind of clinical endpoint study Allergan advocated should be the sole bioequivalency requirement for any Restasis ANDA approval "likely would not be as reliable at detecting differences in the formulation and manufacturing

process of a proposed generic product when the [reference listed drug, i.e., Restasis] shows only a modest clinical effect," particularly given "that such [clinical] trials may present economic and logistical changes for ANDA sponsors." *Id.* at 13. The agency further explained why the studies Allergan demanded "may be limited by confounding variables such as different severities of disease and variability in the definition of the instrument used to measure efficacy, among other issues." *Id.* at 12. It thus concluded that "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic cyclosporine. *Id.* at 13.

137. In rejecting Allergan's arguments, the FDA also considered confidential research Allergan had sent purporting to show a test emulsion could satisfy the draft guidance's in vitro criteria but still demonstrate sufficient variability to make bioequivalence to Restasis in humans unlikely. *Id.* at 22. The FDA rejected this as a basis for altering its guidance, among other reasons, it was "not clear that the emulsions that [Allergan] tested fully satisfied the draft guidance's in vitro criteria." *Id.*

138. Barely a month after the FDA's denial of this citizen petition, Allergan filed another on December 23, 2014. Allergan made much of the FDA's acknowledgment that it was "considering revising" the draft guidance. But as the FDA explained, the fact that the agency was considering input in preparation for releasing final guidance did not mean that it would be unable to receive any Restasis ANDA for substantive review in the interim (i.e., to make the threshold determination that the ANDA was sufficiently complete to permit substantive review), as Allergan would have it. The balance of Allergan's 51-page citizen petition essentially repeated the prior petition's arguments. Allergan made at least four supplements over the next several months, adding to its requests in an August 16, 2015, supplement, in which it again demanded to

know which in vitro methods the FDA intended to apply or accept to determine bioequivalence for Restasis ANDAs. In addition, it requested that the FDA convene a committee of outside experts to evaluate the use of in vitro methods, and that the FDA refuse to receive, review, or approve any ANDAs until the requested evaluation was complete.

139. In the summer of 2015, Allergan also took the opportunity to petition the FDA in response to the "Dear ANDA Applicant" letter the FDA sent soliciting the views of all the ANDA filers. The FDA sought the ANDA applicants' positions on which applicant should be deemed the first filer, in light of the confusion Allergan's Orange Book listings had caused. Though Allergan was not an ANDA filer, it again advocated against the FDA's approval of any Restasis ANDA that was not supported by clinical end-point studies. Ltr. from D. Moxie to Division of Dockets Management (HFA-305), Food and Drug Administration, Re: Docket No. FDA-2015-N-2713—Abbreviated New Drug Applications for Cyclosporine Ophthalmic Emulsion, Sept. 28, 2015. Because, in its view, no ANDA applicant had submitted such clinical endpoint studies, no ANDA was complete and thus none could be first. The FDA has yet to opine publicly on the Dear ANDA Applicant responses, Allergan's related petition, and the first-filer status issues.

140. On February 10, 2016, the FDA once again substantively denied Allergan's citizen petition, granting it only to the limited extent of providing its grounds for doing so—and indicating that it had delayed any consideration of Restasis ANDA approval pending its consideration of Allergan's petition. The FDA noted that the December 2014 citizen petition "repeats many of the assertions that were at the center of Allergan's previous petition" and declined to repeat the FDA's answers. *See* Ltr. from J. Woodcock to D. Moxie & R. Bellantone re Docket Nos. FDA-2015-P-0065 and FDA-2015-P- 1404, Feb. 10, 2016, at 13. The FDA

reminded Allergan that Allergan's "various claims and assertions … are premature" given the draft nature of the guidance. While the FDA agreed to *permit* in vivo studies as part of an ANDA, it did not *require* in vivo studies, as advocated by Allergan. Moreover, the FDA expressed continued doubts about such a study and revised its guidance to recommend that an ANDA applicant contemplating one submit the study protocol to the FDA for review. Elsewhere, the FDA noted that Allergan's claims, many of them repeated from the prior petition, "[n]ot only . . . lack legal support, they also rest on flawed logic." *Id.* at 37.

141. Undeterred, Allergan continued pressing the same arguments, not only in further comments on the (still) draft guidance, *see, e.g.*, Allergan, Inc., Ltr. from D. Moxie to Division of Dockets Management, Food and Drug Administration re Docket No. FDA-2007-D-0369—Comments on October 2016 Draft Guidance on Cyclosporine, Dec. 5, 2016, but in yet another citizen petition, submitted on August 4, 2017. The petition predictably requested that the FDA refuse to accept or approve any pending ANDAs unless supported by in vivo clinical endpoint studies. Just as predictably, on January 2, 2018, the FDA denied the petition. Ltr. From Janet Woodcock to Thomas F. Poché re Docket No. FDA-2017-P-4745, Jan. 2, 2018. In so doing, it noted that Allergan's citizen petition "repeats many of the assertions that were central to" its earlier denied citizen petitions. *Id.* at 4.

142. Allergan did not sue the FDA to challenge denial of any of its petitions.

143. Allergan's baseless petitions nevertheless imposed a burden and delay on FDA action. The FDA denied every one of Allergan's lengthy serial petitions requesting FDA rejection of any Restasis ANDA absent supporting in vivo clinical endpoint studies. *See, e.g.*, Ltr. from J. Woodcock to D. Moxie & R. Bellantone re Docket Nos. FDA-2015-P-0065 and

FDA-2015-P-1404, Feb. 10, 2016, at 30-40. But the FDA was obligated to respond fully to each of these citizen petitions, and those responses took time and resources.

144. As important, Allergan's petitions delayed ANDA approval. In its February 2016 denial of Allergan's December 2014 citizen petition, the FDA stated that it "would not approve or receive any ANDA referencing Restasis" until it responded to each of the points raised in Allergan's citizen petitions (regardless of the merits of Allergan's contentions). *See id.* at 44. In a November 2017 public workshop cosponsored by the FDA and the Federal Trade Commission, Prof. Michael Carrier, author of a leading treatise on antitrust and intellectual property, cited Allergan's citizen petitions as an example of using citizen petitions as a "bottleneck." He asserted that "generics Mylan, Teva, [and] Akorn still cannot enter market because of [Allergan's] Aug. 2017 petition."[8]

145. Allergan's serial petitioning actions thus delayed FDA approval of any Restasis ANDA, and continue to do so, just as Allergan intended.

146. But for Allergan's misconduct, one or several of the ANDA filers would have received FDA approval and would have been able to supply the commercial quantities of generic Restasis necessary to meet market demand upon expiration of the Ding I patent as early as May 17, 2014.

F. Allergan Enters a Sham Agreement with the Saint Regis Mohawk Tribe in a Naked Attempt to Avoid PTAB Invalidation of the Second-Wave Patents

147. Allergan's latest, concurrent effort to forestall competition in the market for cyclosporine stems from a series of IPR requests. In June 2015, Apotex, which subsequently provided Allergan notice of its second-wave patents paragraph IV certifications on July 23,

[8] Michael A. Carrier, *High Prices & No Excuse: 6 Anticompetitive Games*, at 6, presentation at Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), *available at* https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

2015, was the first ANDA applicant to petition the PTAB to initiate an IPR of the second-wave patents. Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that the PTAB would invalidate the second-wave patents. By that time, however, other ANDA applicants, including Mylan and Teva, had also petitioned the PTAB to institute IPR proceedings on the second-wave patents. In December 2016, the PTAB resolved the very same question that the Allergan settlement with Apotex mooted the year before, concluding that there was a reasonable likelihood that each of the second-wave patents would be invalidated upon the PTAB's further review and thereby instituted proceedings against all six of the second-wave patents.[9]

148. On September 8, 2017, Allergan entered into an agreement with the Saint Regis Mohawk Tribe (the "Tribe") to convey ownership of the second-wave patents with an exclusive license back to Allergan for "all FDA-approved uses in the United States" and a promise not to waive its sovereign immunity with respect to any IPR or other administrative action in the PTO related to the Patents. The Tribe did this in exchange for $13.75 million from Allergan, plus potentially $15 million in annual royalties. On September 22, after the Tribe and Allergan agreed to this sham transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity.

149. On February 23, 2018, the PTAB denied the petition. The PTAB confirmed what its precedent had made clear: "There is no statutory basis to assert a tribal immunity defense in

[9] Because the terms of Allergan's settlement with Apotex in December 2015 (that avoided for as much as a year any risk that any of the second-wave patents would be invalidated) were not public, Plaintiffs are presently unable to determine the extent to which that settlement may have violated the antitrust laws and other laws, and thus constitute yet another component in Allergan's overall scheme.

inter partes review proceedings."[10] In fact, the PTAB does not even have personal jurisdiction over the patent owner—its jurisdiction is over the challenged patent.[11] In any event, the PTAB saw through Allergan's ploy, determining that based on the licensing agreement the Tribe had "transferred 'all substantial rights' in the challenged patents back to Allergan,"[12] meaning that for IPR purposes Allergan was still the patent owner, and thus refused to terminate the IPR proceedings. The PTAB set a hearing for April 3, 2018, regarding the merits of the second wave patents and set a June 8, 2018, deadline to issue a written order. Allergan appealed the PTAB's sovereign immunity decision to the Federal Circuit on March 19, 2018, and requested a stay of the PTAB proceedings in the interim, which the Federal Circuit granted on March 28. Order, *Saint Regis Mohawk Tribe et al. v. Mylan Pharms. Inc. et al.*, Case No. 18-1638, slip op. at 2 (Fed. Cir. Mar. 28, 2018).

150. No objectively reasonable litigant could expect these machinations before the PTAB—or Allergan's appeal—to succeed. The district court that issued the decision invalidating the second-wave patents agreed to join the Tribe as a co-plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. The court explained that despite its "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed," it would "adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented." Mem. Op. & Order at 4, 9, *Allergan, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455 (E.D. Tex. Oct. 16, 2017), ECF No. 522.

[10] Decision Denying the Tribe's Motion to Terminate, *Mylan Pharms. et al. v. Saint Regis Mohawk Tribe*, Case IPR2016-01127, Paper No. 130, at 10 (Patent Trial and Appeal Board, Mar. 5, 2018).

[11] *Id.* at 16.

[12] *Id.* at 20.

151. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan's chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid "double jeopardy," that is, to disrupt adjudicative proceedings in one of two venues, even though Allergan itself had initiated proceedings in the other and could voluntarily dismiss the Texas action at any time.

152. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry, and in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry.[13] Licensing the second-wave patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had prior to September 2017, and, from the Tribe's comments, is not made pursuant to a future interest either. Nor was the Tribe acting in its sovereign capacity, *e.g.*, regulating the sale or use of cyclosporine on a reservation, in entering its agreement with Allergan.

G. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I

153. Numerous pharmaceutical manufacturers—including some of the biggest brand and generic pharmaceutical companies in the world—submitted ANDAs seeking the FDA's approval to market generic Restasis. But for Allergan's misconduct as alleged herein, one or more of these ANDA filers would have received FDA approval and would have been able to supply the commercial quantities of generic Restasis necessary to supply the market upon

[13] *See* Saint Regis Mohawk Tribe—Office of Technology and Research, *Frequently Asked Questions about New Research and Technology (Patent) Business*, at 1 ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date."), *available at* https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf.

expiration of Ding I in May 2014. Other ANDA applicants would have been ready at a later date but still within the relevant period.

154. The known manufacturers that have filed ANDAs with the FDA seeking the FDA's approval to market generic Restasis products are identified in the below table:

ANDA Applicant	ANDA No.	When ANDA first submitted, if known	Date Second-Wave Patent paragraph IV certification made
Watson	203463	Nov. 14, 2011	Jan. 2014
Akorn	204561	2012	July 13, 2015
Mylan	205894		July 20, 2015
Teva	203880		July 23, 2015
Apotex	207606		July 23, 2015
InnoPharma (Pfizer subsidiary)	206835	January 13, 2014	Aug. 3, 2015
Famy Care	208469		Jan. 29, 2016
Twi Pharmaceuticals	209064		June 8, 2016
Deva Holding	209811		Nov. 11, 2016

155. Watson was the first company to submit an ANDA. In a May 2014 earnings call Sigurdur Oli Olafsson, then Director and President of Actavis Pharma, confirmed that Watson had "sent in clarifying responses to the questions from the FDA" and that there was "nothing outstanding on us."

156. With respect to Teva's ANDA, it would appear that Teva's original ANDA application (number 203880) was submitted to the FDA close in time to Watson's 2011 submissions (number 203463) because ANDA application numbers are generally assigned by the FDA in the order in which they are received. Allergan has not publicly disputed the sufficiency of Teva's pre-July 2015 ANDA submissions and related certifications.

157. In an August 2016 investors' call, Akorn confirmed that it had "already partnered with someone to manufacture the [Restasis generic] product," that the manufacturing partnership had "already been lined up and filed," and that Akorn had already responded to FDA follow-up

inquiries and was anticipating "product approval hoping in the near future." During a March 22, 2016, earnings call, Akorn CEO Raj Rai indicated that Akorn had submitted its ANDA for Restasis in 2012.

158. Similarly, in an October 2015 earnings call, Mylan's president stated that Mylan remained poised to launch its Restasis generic products upon FDA approval, when he confirmed that Mylan had filed its Restasis ANDA with the FDA "a couple of years back" and was "just waiting to hear from the FDA." In a February 2016 earnings' call, Mylan confirmed that it had received the FDA's acceptance of Mylan's ANDA in the middle of 2015.

159. According to generic manufacturer InnoPharma, Inc. (a Pfizer subsidiary), on July 21, 2015 the FDA deemed its ANDA substantially complete as of the ANDA's original filing date of January 13, 2014. Letter from InnoPharma Licensing LLC to the Food & Drug Admin. at 3, Docket No. FDA-2015-N-2713-0002 (Aug. 26, 2015).

160. Allergan explained that the FDA had notified one ANDA applicant on or about July 9, 2015, that its application had been received, and that the ANDA was "acceptable for review" more than three years before the FDA notified the ANDA applicant that its application had been received.

VI. MARKET POWER AND RELEVANT MARKET

161. The relevant geographic market is the United States and its territories and possessions.

162. Direct evidence demonstrates Allergan's market power. It shows that (a) but for Allergan's conduct, generic versions of Restasis would have entered the market at substantially lower prices than branded Restasis; (b) Allergan's gross margin on Restasis was at all times at least 60%; and (c) Allergan never lowered Restasis prices in response to the pricing of other branded or generic drugs.

163. Allergan doubled the price of Restasis over the past decade.

164. Allergan sold and continues to sell Restasis far in excess of marginal costs and far in excess of the competitive price. It enjoys and continues to enjoy unusually high profit margins.

165. Allergan has held monopoly power conferred by the Ding I patent since 1995 and has enjoyed substantial financial gain from its Restasis monopoly since 2003, when it launched Restasis upon FDA approval.

166. To the extent Plaintiffs need to show market power indirectly, the relevant product market is the sale of cyclosporine ophthalmic emulsion products and consists of Restasis and any AB-rated generic equivalents.

167. At all relevant times, Allergan's share of the relevant market was and remains 100%. In October of 2013, Allergan's vice president of marketing swore under oath that "[a]s there is no other FDA-approved therapeutic treatment for dry eye available on the US market" Restasis owns 100% of the market share." Declaration of Aziz Mottiwala before the U.S. Patent and Trademark Office (Oct. 8, 2013).

168. Branded drugs like Restasis are differentiated based on features and benefits (including safety and efficacy), and not only based upon price. Doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Restasis, in part because insurers typically bear much of the cost of prescriptions. And generic substitution laws in almost every state prevent pharmacists from filling a prescription with a drug that is not an AB-rated equivalent of the prescribed drug. Even drugs within its same therapeutic class do not constrain the price of Restasis.

169. Restasis is not reasonably interchangeable with any products apart from AB-rated generic versions of Restasis. The attributes of Restasis significantly differentiate it from other treatments for dry-eye disease. The FDA does not regard Restasis and other dry-eye disease treatments as interchangeable. Nor does Allergan. When Restasis received FDA approval in December 2002, Allergan characterized Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In filings with the FDA, Allergan has similarly highlighted Restasis' uniqueness: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." Restasis is a topical ophthalmic formulation, and as Allergan has explained, "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

170. Other products are not practical substitutes for Restasis. Artificial tears offer only temporary relief without addressing the underlying causes of dry eye disease. Although corticosteroids can address the inflammation associated with dry eye disease, they have unwanted side effects, as do devices like "punctal plugs" that block the tear ducts and help the eye retain naturally produced tears.

171. At all relevant times, potential entrants into the relevant product market of cyclosporine ophthalmic emulsion faced high barriers to entry due, in large part, to legally and

illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and steep financial costs of entry and expansion.

172. That Allergan has doubled the price of Restasis over the past decade without losing significant sales further demonstrates the lack of substitutability between Restasis and other drug products.

173. Restasis does not exhibit significant, positive cross-price elasticity of demand with any other dry-eye disease medication. Various other treatments for dry-eye disease do exist, but none exhibit cross-price elasticity with—and hence do not constrain the price of—Restasis. The existence of non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales, and therefore those other drug products do not occupy the same relevant antitrust market as Restasis. Shire US, Inc.'s 2016 introduction of its rival dry-eye disease product, Xiidra, for example, has not resulted in lower Restasis prices, thus confirming Allergan's continued market power over the relevant cyclosporine market.[14] Therapeutic alternatives are not the same as economic alternatives.

174. Allergan needed to control only Restasis, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain its Restasis prices without losing substantial sales.

175. Allergan exercised and continues to exercise its monopoly power to exclude competition.

[14] In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an "ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan." Complaint at 1, *Shire US, Inc. v. Allergan, Inc. et al.*, No. 2:17-cv-07716 (D.N.J. Oct. 2, 2017), ECF 1.

VII. MARKET EFFECTS AND CLASS DAMAGES

176. But for the conduct alleged above, generic Restasis would have entered the market early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired.

177. As of 2014, it took the FDA an average of a year and a half to fully approve ANDAs. ANDAs for generic Restasis were submitted as early as two years before the expiration of Ding I in May 2014. The generic manufacturers seeking to sell generic Restasis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic drug products, and manufacturing commercial-launch quantities sufficient to meet market demand.

178. With competition from generic manufacturers approaching, Allergan willfully and unlawfully maintained its Restasis monopoly power through a unified scheme to exclude competition. Allergan's scheme prevented generic competition and had its intended effect of permitting Allergan to maintain supracompetitive monopoly prices for Restasis. Allergan implemented its scheme by fraudulently obtaining the second-wave patents, wrongfully and knowingly submitting these invalid patents for listing in the Orange Book, prosecuting sham patent infringement lawsuits against the putative generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and striking a deal with the Mohawk Tribe in an attempt to insulate the second-wave patents from invalidation in the Patent Office. These acts, individually and in combination, were fraudulent, unreasonably anticompetitive, and unlawful.

179. Had Allergan not defrauded the Patent Office the second-wave patents would not have issued, Allergan would not have been able to list them in the Orange Book, and Allergan could not have initiated sham litigation based on those patents against would-be makers of

generic Restasis. In short, absent the second-wave patents, no patent-based obstacles would have existed after May 2014. In addition, the filing of paragraph IV litigation based on the second-wave patents triggers a 30-month stay of FDA approval.

180. When a brand manufacturer like Allergan submits a citizen petition (or, in this case, multiple petitions), the FDA is obligated to respond to each petition and the specific requests each contains. Had Allergan not submitted sham citizen petitions to the FDA, the FDA would not have been burdened and delayed by its obligation to respond to the petitions.

181. Allergan's conduct had the purpose and effect of foreclosing generic competition to Restasis. Allergan's conduct enabled it to maintain its monopoly, exclude competition in the relevant market, and charge high monopoly prices without losing significant sales. Mylan's CEO, Heather M. Bresch, explained that Allergan's maneuvers had disrupted competition for a "couple of years" and that Mylan is "looking forward to bringing this important product to the market" once Allergan's scheme had run its course.

182. Allergan's exclusionary conduct has unlawfully delayed generic competition and enabled it to sell Restasis without generic competition. But for Allergan's unlawful exclusionary conduct, one or more of the ANDA filers would have begun marketing and selling generic versions of Restasis by May 17, 2014.

183. Allergan's conduct has caused and will cause Plaintiffs and the classes to pay more than they would have paid for Restasis, absent that conduct.

184. Typically, generic versions of branded drugs are initially priced significantly below the corresponding reference listed drug branded counterpart as to which they are AB-rated. As a result, upon generic entry, end-payors rapidly switch from branded drugs to generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions

of a drug predictably decline even further due to competition among the generic firms, and, correspondingly, the branded drug continues to lose even more market share.

185. Price competition enables all purchasers of the drug to buy generic equivalents of a drug at substantially lower prices or to buy the branded drug at reduced prices. Consequently, brand manufacturers have a strong incentive to delay generic competition, and purchasers experience substantial cost inflation from that delay.

186. If generic competitors had not been unlawfully prevented from entering the Restasis market earlier and competing with Allergan, end-payors like Plaintiffs would have paid less for cyclosporine ophthalmic emulsion by (a) purchasing, and providing reimbursement for, AB-rated generic Restasis instead of more-expensive branded Restasis and (b) purchasing, and providing reimbursement for, branded Restasis at lower prices.

187. Allergan's unlawful conduct deprived Plaintiffs and the classes of the benefits of competition that the antitrust laws were designed to guarantee.

VIII. ANTITRUST IMPACT

188. The effect of Allergan's course of monopolistic conduct was to net Allergan billions of dollars in revenue at the expense of end-payors, including Plaintiffs and the proposed classes, who paid hundreds of millions of dollars in unlawful overcharges.

189. During the relevant period, Plaintiffs and class members purchased substantial amounts of Restasis indirectly from Allergan.

190. As a direct and proximate result of Allergan's unlawful conduct, Plaintiffs and class members paid monopoly prices for Restasis that were substantially higher than the prices they would have paid absent Allergan's illegal conduct, because: (1) the price of branded Restasis was artificially inflated as a result of Allergan's illegal conduct, and (2) the class

members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

191. As a result, Plaintiffs and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

192. The overcharges resulting from Allergan's conduct are directly traceable through the pharmaceutical distribution chain to Plaintiffs and other end-payors. A manufacturer first sells the drug to direct purchaser wholesalers based on the listed WAC, minus applicable discounts. Wholesalers then sell the drug to pharmacies, which in turn sell the drugs to consumers. In this short chain of distribution, drug products are not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies, pharmacy benefit managers, and third-party payors (such as health and welfare funds). The products and their prices are thus directly traceable from the manufacturer until they reach the hands of the consumer at a pharmacy.

IX. INTERSTATE AND INTRASTATE COMMERCE

193. Allergan's efforts to monopolize and restrain competition for Restasis have substantially affected interstate commerce.

194. At all material times, Allergan manufactured, marketed, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

195. At all material times, Allergan transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Restasis.

196. In furtherance of its efforts to restrain competition in the relevant market, Allergan employed the U.S. mails and interstate and international phone lines, as well as means of interstate and international travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

197. Allergan's conduct also had substantial intrastate effects in that, among other things, retailers within each state were prevented from offering more affordable generic Restasis to end-payors inside each respective state. The continued absence of competition from generic Restasis directly affects and disrupts commerce within each state.

X. CONTINUING VIOLATIONS

198. Allergan engaged in and continues to engage in a course of wrongful conduct, including conduct within the applicable limitations periods. Allergan's conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Plaintiffs and members of the Damages Class accordingly can recover for damages sustained during the applicable limitations periods.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

For Injunctive Relief under Section 16 of the Clayton Act for Violations of Sections 1, 2, and 3 of the Sherman Act, 15 U.S.C. §§ 1-3
(On behalf of Plaintiffs and the Injunctive Relief Class)

199. Plaintiffs incorporate the above paragraphs by reference.

200. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no

other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

201. Allergan has willfully and unlawfully maintained its monopoly power in the cyclosporine ophthalmic emulsion product market from May 17, 2014, through at least the present. Allergan has done so by executing an overarching scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident. The overarching scheme includes Allergan's fraud before the PTO when obtaining the second wave patents, listing the second wave patents in the Orange Book, filing sham patent infringement litigations based on the second wave patents, filing a series of meritless citizen petitions, and attempting to transfer ownership of the second wave patents to the Tribe to avoid a finding of patent invalidity. In addition, the assignments agreement with the Tribe constituted an unlawful restraint of trade.

202. Plaintiffs and the members of the Injunctive Relief Class have been injured, continue to be injured, and face a continuing threat of injury from Allergan's unlawful conduct, which is ongoing.

203. Allergan knowingly and intentionally engaged in an overarching anticompetitive scheme to maintain its monopoly, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have foreclosed generic competition in violation of antitrust law. This scheme included:

a. prosecuting serial baseless patent applications and ultimately obtaining the second-wave patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;

b. improperly listing the second-wave patents in the Orange Book;

c. asserting the second-wave patents in multiple sham litigations;

d. submitting serial sham citizen petitions to the FDA; and

e. delaying and attempting to evade the PTAB's IPR process through the sham transfer of the second-wave patents to the Tribe.

204. Allergan knowingly and intentionally committed fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), to induce the PTO to grant the second-wave patents. Specifically, Allergan—after repeated denials of previous substantially similar serial applications submitted over the course of a more than a 10-year period—submitted sworn declarations in 2013, that Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by prior art (i.e., Ding I), when in fact Allergan knew that the data presented were neither new nor surprising. Had Allergan made clear to the PTO examiner that the 2013 declaration's statements and data were lifted from prior art known to Allergan for over 10 years—as Allergan's duty of disclosure, candor, and good faith required—the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: the claims presented were all obvious in light of the prior art. Allergan's 2013 misstatements to the PTO were fraudulent and material; Allergan made these representations and omissions knowingly and with the intent to deceive, and these purposeful misstatements and omissions in fact induced the PTO to issue the second-wave patents.

205. Allergan knew when it submitted the second-wave patents for listing in the Orange Book that these patents were fraudulently procured and otherwise invalid as obvious in light of prior art (namely, Ding I and the related patents), and that it was therefore improper to submit the second-wave patents for listing. Allergan knew that the listing of the second-wave

patents in the Orange Book would force ANDA applicants to file paragraph IV certifications, which Allergan knew would allow it to file patent infringement suits against those ANDA applicants. Allergan knew that its lawsuits, despite their objective baselessness, would trigger an automatic stay of FDA final approval of any pending paragraph IV-certified ANDA applicant's generic Restasis product for a period of 30 months—or longer if a court so ordered.

206. Allergan also knew that the listing of the second-wave patents in the Orange Book would create confusion regarding any ANDA first-filer status and chill the FDA's ANDA approval process. Specifically, Allergan knew that listing the second-wave patents in the Orange Book necessarily would alter the order of prioritized review of previously submitted ANDA certifications. Prior to the listing of the second-wave patents to the Orange Book, ANDA filer(s) had certified only as to the Ding I and related patents, which had previously been the only patents listed in the Orange Book for Restasis. Those prior certifications included paragraph II or III certifications for generic cyclosporine products that were intended to be marketed only after expiration of the Ding I and related patents in May 2014. Unlike paragraph IV certifications, those paragraph II or III certifications had not triggered any stay of the FDA's approval process. Listing the second-wave patents in the Orange Book, however, effectuated a stay of the FDA's final approval of any previously paragraph II– or III–certified ANDA and also muddled the prioritized review and approval process for those earlier filed ANDA certifications.

207. Allergan knowingly and intentionally engaged in multiple sham lawsuits against manufacturers of AB-rated generic equivalents of Restasis. In these sham suits, Allergan intentionally and deceptively alleged the generic manufacturers' products infringed its second-wave patents. Allergan knew at all relevant times including at the time of filing these suits that those second-wave patents were wrongfully obtained though fraud on the PTO and were

otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success in the suits; that is, that there was no realistic likelihood that a court would enforce the fraudulently obtained and otherwise invalid second-wave patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a chance of succeeding on the merits of these infringement lawsuits. Allergan filed these sham lawsuits to use a government process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly, regardless of the lack of any actual merit in its infringement claims.

208. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA to delay FDA approval of any of the pending generic ANDA applications, regardless of any objective merit to any part of any petition. Allergan also knew that its citizen petitions would further any confusion it had already created through its Orange Book listing—which independently impeded the FDA's ANDA approval process—regarding which generic, if any, could be accorded "first-filer" status.

209. Allergan knowingly and intentionally transferred the second-wave patents to the Tribe in an attempt (1) to evade or delay the invalidation of the second-wave patents, which reasonably would have been expected to have occurred imminently, in September 2017, but for the delay caused by Allergan's sham transfer, and (2) to evade or delay the end of its cyclosporine ophthalmic emulsion product monopoly.

210. Allergan and the Tribe are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from the agreement, Allergan and the Tribe are economically independent from each other.

211. During the Class Period, Allergan had market power in the market for cyclosporine ophthalmic emulsion. The Tribe was only a participant in this market insofar as the agreement required the Tribe to assert sovereign immunity in an effort to block generic competition and preserve Allergan's Restasis monopoly.

212. In connection with the agreement, Allergan and the Tribe have acted in concert during the IPR proceedings before the PTAB, the sham litigation Allergan instituted in the U.S. District Court for the Eastern District of Texas, and related appeals before the U.S. Court of Appeals for the Federal Circuit. Allergan and the Tribe's concerted actions have had, and continue to have and threaten to have, the purpose and effect of unreasonably delaying the entry of generics in the market for cyclosporine ophthalmic emulsion.

213. There is no valid procompetitive justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

214. Allergan's conduct has affected interstate commerce by keeping the price of cyclosporine ophthalmic emulsion products higher than they would be absent the anticompetitive scheme.

215. By means of the overarching anticompetitive scheme described herein, Allergan has intentionally and wrongfully maintained monopoly power with respect to cyclosporine ophthalmic emulsion products in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. By means of the same scheme, Allergan has also violated Sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1 & 3, by intentionally and wrongfully entering into the agreement and acting in concert with the Tribe to further a conspiracy, the purpose and effect of which was to impose unreasonable restraints on competition in the relevant market and to buttress such restraints

Allergan had previously imposed or furthered via other components of its overarching anticompetitive scheme. As a result of this unlawful maintenance of monopoly power and unlawful conspiracy to restrain trade, Plaintiffs and members of the Injunctive Relief Class have paid and continue to pay artificially inflated prices for their cyclosporine ophthalmic emulsion products.

216. Allergan's anticompetitive conduct as alleged herein is not protected by the *Noerr-Pennington* or state action doctrines.

217. Plaintiffs and members of the Injunctive Relief Class will continue to suffer injury, in the form of monopoly overcharges paid for Restasis, if Allergan's unlawful conduct is not enjoined.

218. Plaintiffs and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Allergan's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

SECOND CLAIM FOR RELIEF

Violation of State Antitrust Law
(On behalf of Plaintiffs and the Damages Class)

219. Plaintiffs incorporate the above paragraphs by reference.

220. In addition to violating Sections 1, 2, and 3 of the Sherman Act and Section 16 of the Clayton Act, Allergan intentionally and wrongfully maintained monopoly power in the relevant market through its overarching anticompetitive scheme in violation of the following state laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1402, 44-1403, *et seq.*, with respect to purchases in Arizona by class members and/or purchases by Arizona residents.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by class members and/or purchases by Arkansas residents.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by class members and/or purchases by California residents.

d. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by class members and/or purchases by California residents.

e. D.C. Code §§ 28-4502, 28-4503, *et seq.*, with respect to purchases in D.C. by class members and/or purchases by D.C. residents.

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

g. Haw. Rev. Stat. §§ 480-2, 480-4, 480-9, *et seq.*, with respect to purchases in Hawaii by class members and/or purchases by Hawaii residents.

h. 740 Ill. Comp. Stat. §§10/3, *et seq.*, with respect to purchases in Illinois by class members and/or purchases by Illinois residents.

i. Iowa Code §§ 553.4, 553.5, *et seq.*, with respect to purchases in Iowa by class members and/or purchases by Iowa residents.

j. Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to purchases in Kansas by class members and/or purchases by Kansas residents.

k. Minn. Stat. §§ 325D.51, 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by class members and/or purchases by Minnesota residents.

l. Mo. Rev. Stat. §§ 407.020, *et seq.*, with respect to purchases in Missouri by class members and/or purchases by Missouri residents.

m. Neb. Rev. Stat. §§ 59-801, 59-802, *et seq.*, with respect to purchases in Nebraska by class members and/or purchases by Nebraska residents.

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by class members and/or purchases by Nevada residents.

o. N.H. Rev. Stat. Ann. §§ 356:2, 356:3, *et seq.*, with respect to purchases in New Hampshire by class members and/or purchases by New Hampshire residents.

p. N.M. Stat. Ann. §§ 57-1-1, 57-1-2, *et seq.*, with respect to purchases in New Mexico by class members and/or purchases by New Mexico residents.

q. N.Y. Gen. Bus. Law § 340 with respect to purchases in New York by class members and/or purchases by New York residents.

r. N.C. Gen. Stat. §§ 75-1, 75-2.1, *et seq.*, with respect to purchases in North Carolina by class members and/or purchases by North Carolina residents.

s. Or. Rev. Stat. §§ 646.725, 646.730, *et seq.*, with respect to purchases in Oregon by class members and/or purchases by Oregon residents.

t. P.R. Laws Ann. tit. 10 §§ 258, 259, 260, *et seq.*, with respect to purchases in Puerto Rico by class members and/or purchases by Puerto Rico residents.

u. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

v. 9 V.S.A. §§ 2453, *et seq.*, with respect to purchases in Vermont by class members and/or purchases by Vermont residents.

w. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by class members and/or purchases by Wisconsin residents.

221. Plaintiffs and members of the Damages Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type that the foregoing laws are intended to prevent, and flow from that which makes Defendant's conduct unlawful.

222. Plaintiffs and the Damages Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF

Unfair Methods of Competition, and Unfair and Deceptive Acts, in Violation of State Consumer Protection Law
(On behalf of Plaintiffs and the Damages Class)

223. Plaintiffs incorporate the above paragraphs by reference.

224. Allergan engaged in unfair methods of competition and unfair, unconscionable, deceptive and fraudulent acts or practices to wrongfully perpetuate its Restasis patent monopoly.

These fraudulent and deceptive acts included intentionally misleading the PTO, the FDA, the courts, and the public about the validity of the claims underlying the second-wave patents.

225. As a direct and proximate result of Allergan's unfair, unconscionable, deceptive, and fraudulent conduct, Plaintiffs and members of the Damages Class were denied the opportunity to purchase generic Restasis, were forced to pay higher prices for Allergan's branded Restasis, and lost money or property as a result.

226. The gravity of harm from Allergan's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiffs and class members could not reasonably have avoided injury from Allergan's wrongful conduct.

227. There was and is a gross disparity between the price that Plaintiffs and class members paid for branded Restasis and the value they received. Much more affordable, bioequivalent generic versions of Restasis would have been available sooner and in greater quantity, and prices for branded Restasis would have been far lower, but for Allergan's unfair, unconscionable, deceptive, and fraudulent conduct.

228. By engaging in such conduct, Allergan violated the following state consumer protection laws:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by class members and/or purchases by Arkansas residents by engaging in unconscionable, false, and deceptive acts and practices.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by class members and/or purchases by California residents by engaging in conduct that is immoral, unethical, oppressive, unscrupulous, and substantially injurious to end-payors. There are no countervailing

benefits to end-payors and any utility of Allergan's conduct is outweighed by the consequences to Plaintiffs and other end-payors. Allergan's conduct also constitutes an unlawful business practice in that it violates Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2.

c. Colo. Rev. Stat. § 6-1-101, *et seq.*, with respect to purchases in Colorado by class members and/or purchases by Colorado residents by engaging in unfair and deceptive acts and practices.

d. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in Pennsylvania by class members and/or purchases by Pennsylvania residents by engaging in unfair methods of competition and unfair and deceptive acts and practices.

e. 9 V.S.A. §§ 2453, *et seq.*, with respect to purchases in Vermont by class members and/or purchases by Vermont residents for personal use by engaging in unfair methods of competition and unfair and deceptive acts and practices.

229. On behalf of themselves and the Damages Class, Plaintiffs seek all appropriate relief provided for under the foregoing statutes.

FOURTH CLAIM FOR RELIEF

Unjust Enrichment Under California Law
(On behalf of Plaintiffs and the Damages Class Members residing in, or who paid and/or provide reimbursement in, California)

230. Plaintiffs incorporate the above paragraphs by reference.

231. This claim is pleaded in the alternative to the other claims in this Complaint.

232. Allergan has reaped and retained substantial benefits in the form of higher profits due to its unjust scheme to monopolize the market for Restasis.

233. The financial benefits to Allergan from its wrongful conduct are traceable to overpayments for Restasis by Plaintiffs and class members.

234. Plaintiffs and class members have conferred upon Allergan an economic benefit—its profits stemming from anticompetitive overcharges. Plaintiffs and class members paid those monopoly overcharges to their substantial economic detriment.

235. It would be futile for Plaintiffs and the class to seek relief against any party with whom they have privity of contract, including the immediate intermediary in the chain of distribution from which they indirectly purchased Restasis. Allergan has paid no consideration to any other person for any of the unlawful benefits it received indirectly from Plaintiffs and the Damages Class with respect to Allergan's sales of Restasis.

236. The financial benefits that Allergan derived by charging supracompetitive prices for Restasis directly and proximately resulted from Allergan's unjust practices described herein. Those benefits rightfully belong to Plaintiffs and the class.

237. It would be wrong and inequitable for Allergan to be permitted to retain any of the ill-gotten gains from its wrongful monopolization scheme.

238. The benefits conferred upon Allergan are measurable, in that the revenue Allergan has earned due to its unlawful overcharges of Restasis is ascertainable by review of sales records.

239. Allergan should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the class all proceeds that it inequitably derived from its scheme, and a constructive trust should be imposed upon such sums.

FIFTH CLAIM FOR RELIEF
For Declaratory Relief under 28 U.S.C. § 2201 for Violations of Sections 1, 2, and 3 of the Sherman Act, 15 U.S.C. §§ 1–3
(On behalf of Plaintiffs and the Injunctive Relief Class)

240. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

241. Plaintiffs and the members of the Injunctive Relief Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201, hereby seek a declaratory judgment that Defendant's conduct in seeking to prevent competition as described herein violates Sections 1, 2, and 3 of the Sherman Act.

XII. PRAYER FOR RELIEF

242. WHEREFORE Plaintiffs, on behalf of the classes, pray for judgment via Court orders:

A. Determining that this action may be maintained as a class action under Fed. R. Civ. P. 23(a), (b)(1), (b)(2) and (b)(3), directing that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the classes, and appointing Plaintiffs as named representatives of the classes;

B. Entering judgment against Allergan and in favor of Plaintiffs and the classes;

C. Awarding treble damages (three times overcharges paid) in an amount to be determined at trial, plus interest in accordance with law;

D. Awarding Plaintiffs and the classes their costs of suit, including reasonable attorneys' fees, as permitted by law;

E. Declaring that Allergan's anticompetitive acts and practices violate Sections 1-3 of the Sherman Act;

F. Granting injunctive relief to correct for the anticompetitive market effects caused by Allergan's unlawful acts and to forbid Allergan from committing such acts in the future; and

G. Entering such other and further relief as may be just and proper.

XIII. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the classes, demand a trial by jury on all issues so triable.

Dated: April 4, 2018

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christina C. Sharp, hereby certify that on April 4, 2018, the foregoing document was served by filing it on the court's CM/ECF system and additionally via electronic mail to all counsel of record.

/s/ *Christina C. Sharp*